

## UNITED STATES PATENT AND TRADEMARK OFFICE



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
09/523,585	03/10/2000	Christopher G M Ken	290252020501	5888		
22249	7590 08/15/2002					
LYON & LYON LLP			EXAMINER			
633 WEST FII SUITE 4700			PHANIJPHAND, GWEN G			
LOS ANGELE	ES, CA 90071		ART UNIT	PAPER NUMBER		
			3731			
			DATE MAILED: 08/15/2002	DATE MAILED: 08/15/2002		

Please find below and/or attached an Office communication concerning this application or proceeding.

,		Application No.		Applicant(s)					
Office Action Summary		09/523,585		KEN ET AL.	F /				
		Examin r		Art Unit					
<u> </u>		Gwen Phanijphand		3731					
Period fo	- ·				dr ss				
- Exte after - If the - If NC - Failu - Any r	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nations of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	e6(a). In no event, however, r within the statutory minimum ill apply and will expire SIX (6	nay a reply be time of thirty (30) days ) MONTHS from t	ely filed will be considered timely he mailing date of this co	mmunication.				
1)🖂	Responsive to communication(s) filed on 10 M	larch 2000 .							
2a)□	This action is FINAL. 2b)⊠ This	s action is non-final.							
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims									
4)⊠ Claim(s) <u>31-44</u> is/are pending in the application.									
1	4a) Of the above claim(s) is/are withdrawn from consideration.								
5) Claim(s) is/are allowed.									
i	6)⊠ Claim(s) <u>31-44</u> is/are rejected.								
ſ	7) Claim(s) is/are objected to.								
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers									
1	The specification is objected to by the Examiner.								
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.									
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).									
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.									
If approved, corrected drawings are required in reply to this Office action.									
12)☐ The oath or declaration is objected to by the Examiner.									
Priority under 35 U.S.C. §§ 119 and 120									
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).									
a) ☐ All b) ☐ Some * c) ☐ None of:									
1. Certified copies of the priority documents have been received.									
2	2. Certified copies of the priority documents have been received in Application No								
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>									
14)□ Ac	knowledgment is made of a claim for domestic	priority under 35 U.S	.C. § 119(e)	(to a provisional a	pplication).				
a)	☐ The translation of the foreign language provicts The translation of the foreign language provicts The translation of the foreign language provicts The translation of the foreign language provides the foreign language	sional application ha	s been receiv	ved.					
Attachment(	s)								
2) Notice 3) Informa	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s) 2.	4) X Intervi 5) Notice 6) Other:	ew Summary (P of Informal Pate	TO-413) Paper No(s). ent Application (PTO-1	<u>2</u> . 52)				
J.S. Patent and Trad PTO-326 (Rev.									

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#### **DETAILED ACTION**

### Claim Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 31, 32, 40, 41, 43, and 44 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,522,836 to Palermo.

Regarding claim 31, Palermo discloses in Fig. 1 a retainer deliverable via a tubular device (100), comprising a core wire (112), a joint (Fig. 2, 118) being electrolytically severable upon application of a current (Abstract) and extending between the distal end of the core wire and at least one array element (108) and the joint. In Figs. 2 and 5, Palermo also discloses the retainer assembly having a first shape when retained within the tubular device (Fig. 2) and a second shape when retainer assembly is not retained in tubular device (Fig. 5) with at least one array element extending outwardly from the joint in the second shape wherein electrolytic severance from core wire the retainer assembly includes a residual joint (Fig. 6).

Regarding claim 32, Palermo discloses in col. 4, ll. 45-47 the core wire covered with an electrical insulation layer.

Regarding claim 40, Palermo discloses in Fig. 5 that when the retainer assembly is in second shape, the residual joint is distal to the proximal deployed end.

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Regarding claim 41, Palermo discloses in Fig. 5 that when the retainer assembly is in the second shape, the residual joint is on the proximal deployed end.

Regarding claim 43, Palermo discloses in Fig. 5 the secondary form approximating the shape of vascular aneurysm.

Regarding claim 44, Palermo discloses in 6 the retainer assembly enclosing a volume and contains a helically wound vaso-occlusive device (Fig. 4, 108).

2. Claims 31, 36, and 42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,690,671 to McGurk et al.

Regarding claim 31, McGurk et al. disclose in Figs. 7 and 8 a retainer deliverable via a tubular device (20), comprising a core wire (30), a joint (10) being electrolytically severable upon application of a current (col. 2, ll. 42-46 and col. 2-5) and extending between the distal end of the core wire and at least one array element (34) and the joint. In Figs.5 and 8, McGurk et al. also disclose the retainer assembly having a first shape when retained within the tubular device and a second shape when retainer assembly is not retained in tubular device with at least one array element extending outwardly from the joint in the second shape wherein electrolytic severance from core wire the retainer assembly includes a residual joint (10).

Regarding claim 36, McGurk et al. disclose in col. 3, ll.49-52 at least one array element comprising of a super-elastic alloy.

Regarding claim 42, McGurk et al disclose in Fig. 11 the proximal deployed end is distal to the proximal delivery end when the retainer is in the second deployed shape.

3. Claims 31, 32, 33, 35, and 36 through 43 are rejected under 35 U.S.C 102(b) as being clearly anticipated by U.S. Patent No. 5,354,295 to Guglielmi et al.

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Regarding claim 31, Guglielmi et al. disclose in Fig. 3 a retainer deliverable via a tubular device (44), comprising a core wire (42), a joint (50, 54) being electrolytically severable upon application of a current (col. 5, Il. 44-47 and col. 6, Il. 19-20) and extending between the distal end of the core wire and at least one array element (56, 58) and the joint, and a retainer assembly comprising at least one array element. In Figs. 7 and 8, Guglielmi et al. also disclose the retainer assembly having a first shape when retained within the tubular device (col. 4, Il. 33-37) and a second shape when retainer assembly is not retained in tubular device (col. 4, Il. 44-46) with at least one array element extending outwardly from the joint in the second shape wherein electrolytic severance from core wire the retainer assembly includes a residual joint (Fig. 5).

Regarding claim 32, Guglielmi et al. disclose in col. 6, ll. 20-21 the core wire is covered with an electrical insulation layer.

Regarding claim 33, Guglielmi et al. disclose in col. 7, l. 67 at least one array element comprising platinum.

Regarding claim 35, Guglielmi et al. disclose in col. 7, 1. 35 at least one array element comprising stainless steel.

Regarding claim 37, Guglielmi et al. disclose in col. 4, ll. 29-30 a portion of at least one array element covered by radio-opaque material.

Regarding claim 38, Guglielmi et al. disclose in col. 7, 1. 67 and col. 4, 11.29-30 a radioopaque material being platinum.

Regarding claim 39, Guglielmi et al. disclose in Fig. 4 that when the retainer assembly is in the second deployed shape, at least one array element terminates from the joint.

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Regarding claim 40, Guglielmi et al. disclose in Fig. 3 that when the retainer assembly is in second shape, the residual joint is distal to the proximal deployed end.

Regarding claim 41, Guglielmi et al. disclose in Fig. 4 that when the retainer assembly is in the second shape, the residual joint is on the proximal deployed end.

Regarding claim 42, Guglielmi et al. disclose in Fig. 4 the proximal deployed end is distal to the proximal delivery end when the retainer is in the second deployed shape.

Regarding claim 43, Guglielmi et al. disclose in Fig. 4 the secondary form approximating the shape of vascular aneurysm.

Regarding claim 44, Guglielmi et al. disclose in Figs. 1A and 4 the retainer assembly enclosing a volume and contains a helically wound vaso-occlusive device (col. 9, ll. 21-23).

# Claim Rejections - 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guglielmi et al. in view of U.S. Patent No. 5,639,277 to Mariant et al.

Regarding claim 34, Guglielmi et al. disclose an implantable retainer but do not disclose at least one array element comprising of tantalum. Mariant et al., however, disclose vaso-occlusive coils made out of a variety of materials. Mariant et al. teach in col. 1, ll.53-55 and col.

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4, ll.13-18 the addition of tantalum, which is radio-opaque. It is advantageous to add tantalum because some portion of the coil should be radio-opaque, allowing the coil's position to be monitored. It would have been obvious to one of ordinary skill in the art at the time of the invention to compose an array element from tantalum because this allows the array element to be viewed from outside the body, allowing supervision of the array element's location.

Regarding claim 36, Guglielmi et al. disclose an implantable retainer but do not disclose at least one array element comprising of a super-elastic alloy. Mariant et al., however, disclose vaso-occlusive coils made out of a variety of materials. In col. 3, ll.66-67 and col.4, ll.1-3, 13-15, Mariant et al. disclose alloys and elastic polymers such as polyethylene as being suitable materials for composing vaso-occlusive coils. These materials are advantageous because they are biocompatible. It would have been obvious to one of ordinary skill at the time of the invention to compose an array element from a biocompatible material to prevent infection and other surgical complications.

## Obviousness-type Double Patent

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 31-40 and 42-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 12-15 of U.S. Patent No. 6,086,577. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Regarding claim 31, U.S. Patent No. 6,086,577 discloses in claim 1 a retainer deliverable via a tubular device comprising a core wire, a joint being electrolytically severable upon application of a current and extending between the distal end of the core wire and at least one array element and the joint, and a retainer assembly comprising at least one array element.

Retainer assembly having a first shape when retained within the tubular device and a second shape when retainer assembly is not retained in tubular device with at least one array element extending outwardly from the joint in the second shape wherein electrolytic severance from core wire the retainer assembly includes a residual joint.

Regarding claim 32, U.S. Patent No. 6,086,577 discloses in claims 1 and 2 the core wire covered with an electrical insulation layer.

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Regarding claim 33, U.S. Patent No. 6,086,577 discloses in claims 1 and 3 at least one array element comprising of platinum.

Regarding claim 34, U.S. Patent No. 6,086,577 discloses in claims 1 and 4 at least one array element comprising of tantalum.

Regarding claim 35, U.S. Patent No. 6,086,577 discloses in claims 1 and 5 at least one array element comprising of stainless steel.

Regarding claim 36, U.S. Patent No. 6,086,577 discloses in claims 1 and 6 at least one array element comprising of a super-elastic alloy.

Regarding claim 37, U.S. Patent No. 6,086,577 discloses in claims 1 and 7 a portion of at least one array element covered by radio-opaque material.

Regarding claim 38, U.S. Patent No. 6,086,577 discloses in claims 1, 7, and 8 the radioopaque material being platinum.

Regarding claim 39, U.S. Patent No. 6,086,577 discloses in claims 1 and 9 that when the retainer assembly is in a second deployed shape, at least one array element terminates from the joint.

Regarding claim 40, U.S. Patent No. 6,086,577 discloses in claims 1 and 12 that when the retainer assembly is in second shape, the residual joint is distal to the proximal deployed end.

Regarding claim 42, U.S. Patent No. 6,086,577 discloses in claims 1 and 13 the proximal deployed end is distal to the proximal delivery end when the retainer is in the second deployed shape.

Regarding claim 43, U.S. Patent No. 6,086,577 discloses in claims 1 and 14 the secondary form approximates the shape of vascular aneurysm.

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Regarding claim 44, U.S. Patent No. 6,086,577 discloses in claims 1 and 15 the retainer

assembly encloses a volume and contains a helically wound vaso-occlusive device.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure.

U.S. Patent No. 5,496,330 to Bates et al.

U.S. Patent No. 5,108,407 to Geremia et al.

U.S. Patent No. 4,425,908 to Simon

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Gwen Phanijphand whose telephone number is 703-305-4845.

The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-305-3590 for regular

communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is 703-308-0858.

GP

August 5, 2002

Gwen Phanijphand

Patent Examiner

Art Unit 3731

Michael J. Milano

Supervisory Patent Examiner

Technology Center 3700